HOWARD UNIVERSITY
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Excellence in Truth and Service

Office of Regulatory Research Compliance

DATE: November 16, 2026

RE: STATEMENT OF COMPLIANCE

The Howard University (HU) Office of Regulatory Research Compliance (ORRC/Institutional Review Boards (IRBs) operates in accordance with all applicable federal and state laws, regulations, and guidance governing human subjects research, including requirements established by the U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) under HU Federal-Wide Assurance (FWA Expiration Date:09/06/2027) #00000891. The HUIRBs comply with 45 CFR Parts 46, 21 CFR Parts 50, 56, 312, 812; and 45 CFR 164.508-514; the International Council for Harmonization (ICH) E6 Good Clinical Practice (GCP) Guidelines, to the extent required by the FDA and the Health Insurance Portability and Accountability Act (HIPAA). For Department of Defense (DoD) supported human subjects research, the HU compliance program comply with all applicable DoD requirements, including the informed consent provisions of 32 CFR 219.116 and Department of Defense Instruction (DoDI) 3216.02, as well as any additional DoD human research protection requirements that apply to the conduct, review, and oversight of such research.

The HU/ORRC Institutional Animal Care and Use Committee (IACUC), through the Animal Research Protection Program (ARPP), ensures compliance with federal regulations from the Office of Laboratory Animal Welfare (OLAW) and ethical standards from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the Animal Welfare Act (AWA), and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.

As part of the HU/ORRC research oversight responsibility, the HU Institutional Biosafety Committee (IBC) ensures the safe handling, storage, and disposal of biological materials by overseeing research using recombinant or synthetic nucleic acid molecules and experimentation involving biological materials (e.g., infectious agents) and other potentially hazardous agents (e.g., carcinogens). In so doing, it implements policies, procedures, and training to mitigate risks and ensure compliance with regulatory requirements from the National Institutes of Health (NIH) Office of Science Policy (OSP).

Congruent with sound radiation safety oversight, the HU/ORRC Radiation Safety Committee (RSC) complies with all applicable United States Nuclear Regulatory Commission (USNRC) regulations under 10 CFR Parts 19, 20, 30, 34, 35, and 37, and the District of Columbia Department of Health (DC-DoH) regulations governing radiation safety.

Notably, the HU compliance program complies with applicable research security and compliance requirements, including National Security Presidential Memorandum-33 (NSPM-33), the Export

Administration Regulations (EAR) 15 CFR Parts 730-774, and the International Traffic in Arms Regulations (ITAR) 22 CFR Parts 120-130.

To promote objectivity in research, prevent bias resulting from financial conflicts of interest, or the appearance of bias, in the design, conduct, and reporting of a sponsored project, the ORRC adheres to federal research integrity standards and complies with 42 CFR Parts 50 and 93, and 45 CFR Parts 680 and 689.

Collectively, the institutional oversight committees are duly constituted, as required by Federal regulations, to ensure a fair and thorough review process.

Thomas Obisesan

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